



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bonnie M. Davis

Serial No.: 09/856,282

Group No.: 1614

Filed: June 18, 2001

Examiner: Jones, Dwayne, C

For: Dosage Formulations For Acetylcholinesterase Inhibitors

Attorney Docket No.: U 013469-7

Declaration

I, Bonnie Davis of 160 Cold Spring Road, Syosset, New York declare as follows:

1. I am the inventor of the patent application under consideration
2. I have been asked to explain the difference between the term "delay" as used in the present application and terms such as "prolonged" or "sustained" when used to refer to various prior art drug formulations.
3. The difference is I believe clear from a reading of the present application. The purpose of the invention is to delay the activity of the acetylcholinesterase inhibitor that is used for a period (see page 2 line 13 to 14) so as to prevent such activity at a time when such activity is undesired. It is particularly important that activity of the drug be minimized during sleep. There is of course always a risk that some drug "leak" from any formulation. But the object of the delay in the present invention is that there should to the extent possible be a period of zero release so that during the period corresponding to sleep little or no cholinesterase inhibition occurs. This is the meaning of references to delayed release in the present application.
4. This contrasts with sustained or prolonged release formulations which have been described previously. In such cases, the objective was to allow for a steady release of the drug, it being thought that fluctuations in the levels of inhibitor were not desired. Such formulations

therefore did not provide for any period in which the objective was zero release of drug. The present invention is based on the realization that the assumptions underlying the design of sustained release inhibitors were wrong and that one needed a period of as little release as possible in order to allow patients to get a good night's sleep.

5. All statements made of herein of my own knowledge are true and that all statements made on information and belief are believed to be true.

I make this declaration in the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon.

Bonnie M. Davis
Bonnie M. Davis

8/10/06
date